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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,166	09/10/2001	Tadashi Kokubo	06082.0026	9560

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,166

Applicant(s)

KOKUBO ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2004 has been entered.

Claims 1-8, 10-15 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "combination of a catheter and microsphere" in claim 15 renders the claim ambiguous, because it is not clear for what type of inventive category is applicant seeking protection. Is the claim directed to a "kit," a "composition," or a method? Applicant is requested to amend the claim to clearly indicate the inventive category of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-5, 7-8, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547.

Gray discloses particulate material comprising ceramic microspheres having a diameter in the range of 5 to 200 microns wherein the microsphere is made of 99.99% pure yttria (Y_2O_3) (see claim 1, and col 7, lines 1-66). Gray discloses methods of preparing such particulates by preparing a microsphere and then subjects the microspheres to neutron beams to product beta-radiation emitting radionuclide of yttrium-90 (col 7, lines 35-37). Thus, Gray meets the limitations of claims 1 and 8.

Gray also teaches the process of melting aggregates of yttria a thermal or plasma spray drying. (col 5, line 34-45; col 6, lines 25-40). Gray further irradiates its yttria aggregates with neutron beams to produce radioactive microspheres. (col 5, lines 50-55). Gray fails to specifically state that his microspheres are in the

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shape of a sphere or that his microspheres contain 47% by weight of radioactive yttrium.

Modifying the shapes of microspheres are viewed to be a design choice and absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the shape of Gray's microspheres to enhance its clinical efficacy.

Furthermore, it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33 (CCPA 1937). *In re Russell*, 439 F.2nd 1228, 169 U.S.P.Q. 426 (CCPA 1971). Accordingly, absence the showing of criticality, it would have been *prima facie* obvious to optimize radioactive percentages of yttrium in microspheres of Gray by routine experimentation, because the ordinary artisan would have had a reasonable expectation of success in achieving the desirable clinical outcome by modifying such characteristics of Gray's microspheres.

Claims 1-5, 8, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547 in view of Day US Patent 5,302,369.

Gray's teachings are described above. Gray also teaches the use of other ingredients such as silica in his microspheres (col 4, lines 16-26). Gray fails to explicitly teach oxide crystals consisting essentially of a mixture of Y₂O₃ and YPO₄. Gray does not explicitly elaborate on administration of his microspheres with a catheter.

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Day is used to teach that yttrium can be incorporated into the microspheres in combination with phosphorus and oxygen in the form of yttrium phosphates (see col 6, lines 40-62; col 16, lines 63-64; UMR-14, table II). Day provides adequate expectation of success when microspheres are in the spherical form. Day also teaches that his microspheres are administered via a catheter. (col 7, lines 45-47).

Since both the microspheres of Day and Gray are used for the same purpose, it would have been obvious to one of ordinary skill in the art at the time of invention to combine yttrium oxides of Gray with the yttrium phosphate mixtures of Day, because it has been held to be prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Furthermore, as taught by Day, catheters are employed to administer radioactive microspheres, therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a catheter to administer the microspheres of Gray to a patient in need thereof.

Claims 1-8, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray US Patent 5,885,547 in view of Day US Patent 5,302,369 and further in view of Huang US Patent 5,073,404.

The teachings of Gray and Day are described above. Day indicates that radioactive microspheres can contain silica and/or further be coated with

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additional coating material to control the leaching of radioactive material (col 1, line 45-col 2, line 14; col 4, lines 1-14; col 5, lines 1-28; col 15, lines 1-62).

However, the combined teachings of Gray and Day fail to explicitly provide for coating of their micropsheres with silica.

Huang is merely used to show the conventional nature of using silica compositions in coating transparent glass microspheres and its potential benefits as antireflective and protective coating for the purposes of preventing leaching (abstract, col 1, lines 53-col2, line 55).

Accordingly, It would have been obvious to one of ordinary skill in the art to coat the radioactive micropsheres of Gray and Day with a suitable coating material such as silica, because as taught by Day, itself, and described by Huang, the ordinary skill in the art would have had a reasonable expectation of success in controlling the leaching of radioactive material from the core composition to protect the radioactive microglasses and further improve the antireflective and protective properties of such microspheres.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-

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272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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